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Date: October 16, 2007 Name: Richard E. Stanley, Jr. Signature: /Richard E. Stanley, Jr./ Reg. No. 45,662

Our Case No. 8627-368
Client Ref. No. PA-5469-RFB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Darin G. Schaeffer et al.

Serial No.: 10/756,851

Filing Date: January 14, 2004

For: INTRODUCER

Examiner: Timothy J. Neal

Group Art Unit No.: 3731

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action dated August 14, 2007, Applicants request review of the final rejection in the above-identified application. As explained in more detail below, this review is being requested because of errors in the Examiner's rejections and the omission of elements needed for a prima facie rejection. A Notice of Appeal accompanies this Request.

The Examiner has rejected claims 1-5, 8-10, 12-14, 18, 22-26, 29-31, 33-35 and 39 as being unpatentable under 35 U.S.C. § 103(a) over Figures 1-8 of Applicants' specification. The Examiner has also rejected claims 6-7, 11, 15-17, 19-20, 27-28, 32, 36-38 and 40-41 as being unpatentable under 35 U.S.C. § 103(a) over Figures 1-8 of Applicants' specification in view of Stephens (U.S. Patent No. 6,224,586) or McIvor (U.S. Patent No. 6,213,988). The Examiner has not specifically addressed pending claim 21.

Applicants respectfully submit that the Examiner is improperly relying upon a hindsight reconstruction of Applicants' claims as the basis for the present rejections. Moreover, as explained below, the basis for the Examiner's obviousness rejections fails to disclose all of the limitations of several of Applicants' claims.

The Supreme Court has repeatedly emphasized that it is improper for an Examiner to reject an applicant's claims based upon unsupported, after-the-fact reasoning. *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1397 (U.S. 2007) ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning."); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 36 (1966) (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight."); *see also* MPEP § 2142 ("The tendency to resort to 'hindsight' based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.").

Hindsight reasoning is prohibited by 35 U.S.C § 103(a) which requires an examiner to consider the patentability of the claimed subject matter "as a whole." Likewise, 35 U.S.C. § 103(a) requires that "[p]atentability shall not be negatived by the manner in which the invention was made." The Federal Circuit has explained that the ultimate question under 35 U.S.C. § 103 is "whether the claimed invention *as a whole* would have been obvious," "not whether the differences *themselves* [between the prior art and the claimed invention] would have been obvious." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537 (Fed. Cir. 1983) (emphasis in original); *see also Schenk v. Norton Corp.*, 713 F.2d 782, 785 (Fed. Cir. 1983).

In order to support an obviousness rejection, the Supreme Court requires the examiner to identify "an apparent reason to combine the known elements in the fashion claimed." *KSR*, 82 USPQ2d at 1396. As noted by the Federal Circuit, the fact that "all elements of an invention may have been old (the normal situation), or some old and some new, or all new, is however, simply irrelevant. Virtually all inventions are

combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art." *Environmental Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 698 (Fed. Cir. 1983).

Claims 1 and 21-22 require an introducer that is made from a flexible plastic material. A slot is required that extends through a wall of the introducer and along the entire length of the introducer. Claims 1 and 21 also require that the introducer have a beveled distal end. Claims 21 and 22 also require that the introducer have a flanged proximal end. The Examiner has rejected claims 1 and 21-22 as being obvious over the combination of Figures 1-8 which are disclosed in Applicants' specification. Figures 1-8 disclose three different prior art introducers. The first prior art introducer, shown in Figures 3-4, is made from rigid metal and has no slot. The second prior art introducer, shown in Figures 5-6, is made from rigid metal and has a slot. The third prior art introducer, shown in Figures 7-8, is made of plastic and has no slot. Essentially, the Examiner is arguing that it would have been obvious to modify the first prior art introducer by adding the slot from the second prior art introducer. This would result in a rigid metal introducer with a beveled distal end, a flanged proximal end, and a slot. Next, the Examiner argues that it would have been obvious modify the combination of the first and second prior art introducers by changing the material from a rigid metal to plastic because the third prior art introducer is made from plastic.

However, the Examiner's obviousness rejections suffer from several failings. First, the prior art actually teaches away from the proposed modifications. It is undisputed that the only prior art introducer which had a slot was made from rigid metal. Thus, one of ordinary skill in the art would have reasonably concluded from the prior art that rigid metal was the material of choice when a slot was desired. The reason that rigid metal would have been considered the desirable design choice for a slotted introducer is that the introducer must have sufficient longitudinal and circumferential integrity to withstand the pressure of the hemastatic valve as the introducer is being pushed through the valve. Therefore, it would not have been obvious to one of ordinary skill in the art from the prior art that the Examiner has cited that a slotted introducer could be made from a flexible plastic instead of a rigid metal. Indeed, the inventor has submitted a declaration to the Examiner addressing this specific issue. (Schaeffer

Declaration ¶ 7). However, the Examiner has failed to give proper weight to the inventor's declaration. *In re Sullivan*, 84 USPQ2d 1034, 1040 (Fed. Cir. 2007) ("[W]hen an applicant puts forth relevant rebuttal evidence, as it did here, the Board must consider such evidence. The claimed composition cannot be held to have been obvious if competent evidence rebuts the prima facie case of obviousness. By failing to consider the submitted evidence, the Board thus committed error.").

Second, Applicants identified an unrecognized problem, and thus, satisfied an unmet need. Specifically, the only slot that is disclosed in a prior art introducer is in a rigid metal introducer (i.e., the second prior art introducer). Because the slot is not flexible, it is required to be relatively large to allow the stented catheter to be inserted into the slot or the introducer to be removed from the stented catheter. This causes the overall diameter of the second prior art introducer to be large and difficult to insert through a standard hemastatic valve. (Specification at ¶ [0030]). On the other hand, the only introducer disclosed in the prior art that was made from plastic has no slot and has a continuous circumferential wall (i.e., the third prior art introducer). This introducer can be smaller in overall diameter to make insertion into the hemastatic valve easier, but the introducer cannot be removed from the stented catheter after insertion because there is no slot. (Specification at ¶ [0032]). There is no evidence in the record that anyone with ordinary skill in the art recognized these problems. Thus, the inventors conceived of a device with tangible advantages over the prior art that was unmet with any other device. The Examiner seems to downplay the significance of Applicants' invention by arguing that "[i]t appears to the Examiner that the Applicant has taken the best features of the three embodiments and combined them into one device." (Office Action at 4). However, Applicants respectfully submit that this type of analysis is expressly prohibited by 35 U.S.C. § 103(a), which states that "[p]atentability shall not be negatived by the manner in which the invention was made."

Third, claims 14, 17, 19, 20, 24, 33, 35, 38 and 40-41 require that the introducer have a beveled distal end and that the slot is disposed at the heel of the bevel. The only prior art introducer with a slot has a blunt distal end, not a beveled distal end. In other words, the prior art suggests that a blunt distal end is preferable when a slot is provided, and that when a beveled distal end is used, it is preferable to not have a slot

in the introducer. Moreover, even if one of ordinary skill in the art were to modify the first and second prior art introducers by adding a slot (i.e., the second introducer) to the metal introducer with a beveled distal end (i.e., the first introducer), there would still be no teaching of where to put the slot relative to the beveled distal end since no prior art reference shows how to combine a slot with a beveled distal end. Furthermore, even assuming that one of skill in the art were to combine the first and second prior art introducers to achieve a slotted introducer with a beveled distal end, the modified introducer would be made of rigid metal, not a flexible plastic (i.e., both the first and second prior art introducers are rigid metal). The prior art provides no motivation to make this further modification because the third prior art introducer, which is made from plastic, neither has a slot nor has a beveled distal end.

Fourth, claims 8-10, 13, 29-31, 34-35 and 39 require that the width of the slot be less than the diameter of the medical instrument to be inserted into the introducer; less the fifty percent of the diameter of the medical instrument; or substantially closed in a free state. The only slot that is disclosed in the prior art introducers is wider than the diameter of the medical instrument. As noted above, one reason for this is because the slotted introducer (i.e., the second introducer) is made from rigid metal. Thus, the prior art slot was not flexible and could not be opened to insert the medical instrument or remove the introducer from the medical instrument. Instead, the width of the rigid slot of the second prior art introducer is required to be larger than the diameter of the medical instrument. In other words, even if all three prior art introducers were combined, the slot of the proposed combination would be wider than the medical instrument instead of being narrower than the medical instrument as Applicants have claimed. The Examiner has provided no articulated reasoning for making this additional modification to the prior art. Moreover, it would not be obvious to narrow the width of the slot because a physician would then be required to stretch the slot open when inserting the medical instrument or removing the introducer which could cause the edges of the slot to undesirably contact and rub against the stented catheter.

Accordingly, Applicants request reconsideration and allowance of the application.

Respectfully submitted,

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